least a portion of the self-expanding stent prior to deployment of the self-expanding stent;

delivering the delivery system to a region of a vessel to be repaired;

releasing a portion of the self-expanding stent to a position corresponding with a marker band on the catheter;

re-constraining the self-expanding stent;

implanting the self-expanding stent into a wall of the vessel to be repaired; and

inflating the inflatable device to assist expansion of the self-expanding stent.

REMARKS

Claims 1-44 are pending in the application. By this Amendment, Applicant proposes to amend claims 1, 5, 17, 29, and 31. No new matter has been added. Applicant respectfully requests reconsideration and allowance of the pending claims.

Initially, Applicant thanks Examiner Landrem for indicating that claims 36-43 are allowed, and that claims 5, 6, and 31 contain allowable subject matter. In the Office Action Summary and on page 5 of the Office Action, the Examiner indicates that claim 31 is objected to, but would be allowable if rewritten in independent form. However, on page 2 of the Office Action, the Examiner includes claim 31 in the list of claims rejected under 35 U.S.C. § 102(b). Based on the features of claim 31, Applicant understands the inclusion of claim 31 in the list of rejected claims was in error. If this understanding is not correct, Applicant requests clarification from the Examiner. Applicant has

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amended claims 5 and 31 to place these claims in independent form, and based on Applicant's understanding, claims 5, 6, and 31 therefore are in condition for allowance.

In the Office Action, claims 1-4 and 7-35 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,743,874 to Fischell et al. (Fischell). In addition, claim 44 was rejected over Fischell in view of U.S. Patent No. 5,695,499 to Helgerson. Applicant respectfully traverses these rejections.

Regarding claim 1, Fischell does not disclose or suggest a stent delivery system comprising, *inter alia*, "a tubular member including a first marker band proximate a position corresponding to a leading end of a self-expanding stent, a second marker band proximate a position corresponding to a trailing end of the self-expanding stent to indicate a position of the trailing end, and a third marker band between the first and second marker bands and between the leading and trailing ends of the stent." Instead, Fischell discloses an integrated catheter including a proximal radiopaque marker 182 at a proximal end of a self-expanding stent 160 and a distal radiopaque marker 180 at a distal end of the self-expanding stent 160. Fischell also discloses a radiopaque band 152 at a center of an interior chamber 151 of an inflatable balloon 150. As shown in FIG. 4, the radiopaque band 152 does not correspond to any of the claimed marker bands -- it is not proximate the leading end of the stent; it is not proximate the trailing end of the stent to indicate a position of the trailing end; and it is not between the ends of the stent. Moreoaver, none of the radiopaque markers 180, 182 or band 152 is between the leading and trailing ends of the stent 160. Fischell therefore does not disclose or suggest the claimed arrangement of marker bands.

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The Examiner asserts Fischell's disclosure of "one, two, or more radiopaque markers could be used with any integrated design" anticipates the claimed relationship of marker bands. This disclosure simply teaches that more than two markers can be used with a catheter. It teaches nothing about their relative positions on the catheter. More specifically, regardless of the number of markers that Fischell discloses could be used, Fischell still does not disclose or suggest a tubular member having a first marker band, a second marker band, and a third marker band between the first and second marker bands and between the leading and trailing ends of the stent, as recited in claim 1. Accordingly, the § 102(b) rejection of claim 1 should be withdrawn.

With respect to independent claims 17 and 29, the Examiner appears to indicate that Fischell does not disclose or suggest "that the balloon is positioned beneath at least a portion of the stent prior to deployment." (See Office Action at page 5.) Applicant has amended claim 17 to recite a method for implantation of a self-expanding stent including, *inter alia*, "providing a delivery system including ... an inflatable device provided on [a] catheter and positioned beneath at least a portion of [a] self-expanding stent prior to deployment of the self-expanding stent." Similarly, Applicant has amended claim 29 to recite a self-expanding stent and delivery system including, *inter alia*, "at least a portion of [a] self-expanding stent overlapping at least a portion of [an] inflatable device prior to deployment of the self-expanding stent."

As discussed in Applicant's previous communications, Fischell discloses an integrated catheter having, in one embodiment, a balloon 50 axially separated from a stent 60 by a marker band 80 and, in another embodiment, a balloon 150 axially separated from a stent 160 by a radiopaque marker 182. In either embodiment, Fischell

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does not disclose or suggest the balloon 50, 150 positioned beneath any portion of the stent 60, 160 prior to deployment of the stent 60, 160.

The Examiner asserts that Fischell discloses the inflatable device 50 positioned below the distal portion of the self-expanding stent at column 3, lines 52+. However, the positioning of the inflatable device 50 below the distal portion of the stent occurs after deployment (i.e., radial expansion) of the stent. *See* Fischell, col. 3, lines 49-54. Therefore, Fischell does not disclose or suggest an inflatable device provided on the catheter and positioned beneath at least a distal portion of the self-expanding stent prior to deployment of the stent, as recited in claim 17, or at least a portion of the self-expanding stent overlapping at least a portion of the inflatable device prior to deployment of the self-expanding stent, as recited in claim 29. Accordingly, the § 102(b) rejections of claims 17 and 29 should be withdrawn.

With regard to independent claim 44, Fischell does not disclose or suggest, *inter alia*, providing a delivery system including "an inflatable device provided on [a] catheter and positioned beneath at least a portion of [a] self-expanding stent prior to deployment of the self-expanding stent," for reasons similar to those discussed above in connection with claims 17 and 29. Furthermore, Helgerson does not overcome the above-noted deficiencies of Fischell and is not relied upon for such teachings. Instead, Helgerson is only relied upon for its alleged teaching of re-constraining a stent. Accordingly, the § 103(a) rejection of claim 44 should be withdrawn

Claims 2-4, 6-16, 18-28, 30, and 32-35 depend from either claim 1, 5, 17, or 29, and are therefore allowable for at least the same reasons claim 1, 5, 17, or 29 is allowable.

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Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 1-44 in condition for allowance. Applicant submits that the proposed amendments of claims 1, 5, 17, 29, 31, and 44 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Applicant respectfully requests entry of this Amendment, reconsideration of this application, withdrawal of the claim rejections, and timely allowance of the pending claims.

The Office Action contains numerous characterizations of the invention, the claims, and the related art, with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call Applicant's undersigned attorney at 202-408-4252.

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If there are any fees due in connection with this submission, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: **July 21, 2003**

By: _____
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APPENDIX

Comparison of Amended Claims to Currently Pending Claims

IN THE CLAIMS:

Please amend claims 1, 5, 17, 29, 31, and 44 as follows:

1. (Twice Amended) A delivery system for a self-expanding stent, the delivery system comprising:

a catheter having a distal end, the catheter being configured to retain a self-expanding stent proximate the distal end, the catheter including

a tubular member including a first marker band proximate a position corresponding to a leading end of a self-expanding stent, a second marker band proximate a position corresponding to a trailing end of the self-expanding stent to indicate a position of the trailing end, and a third marker band between the first and second marker bands and between the leading and trailing ends of the stent, and

an outer member positioned about the tubular member; the outer member being slidable relative to the tubular member in an axial direction; and

an inflatable device provided on the catheter and positioned proximate the distal end.

5. (Twice Amended) [The delivery system of claim 1, further comprising] A delivery system for a self-expanding stent, the delivery system comprising:

a catheter having a distal end, the catheter being configured to retain a self-expanding stent proximate the distal end, the catheter including

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a tubular member including a first marker band proximate a position corresponding to a leading end of a self-expanding stent, a second marker band proximate a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands, and

an outer member positioned about the tubular member; the outer member being slidable relative to the tubular member in an axial direction;

an inflatable device provided on the catheter and positioned proximate the distal end; and

a loading funnel, the loading funnel being configured to be removably attachable to [the] a distal end of the tubular member.

17. (Twice Amended) A method for implantation of a self-expanding stent, the method comprising:

providing a delivery system including a self-expanding stent, a catheter having a distal end and being configured to retain the self-expanding stent proximate the distal end, and an inflatable device provided on the catheter and positioned beneath at least a portion of the self-expanding stent prior to deployment of the self-expanding stent;

delivering the delivery system to a region of a vessel to be repaired;

implanting the self-expanding stent into a wall of the vessel to be repaired; and

inflating the inflatable device to assist expansion of the self-expanding stent.

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29. (Amended) In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

a self-expanding stent;

a catheter having a distal end, the catheter being configured to retain the self-expanding stent proximate the distal end; and

an inflatable device provided on the catheter, at least a portion of the self-expanding stent overlapping at least a portion of the inflatable device prior to deployment of the self-expanding stent.

31. (Amended) [The combination of claim 2, further comprising] In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

a self-expanding stent;

a catheter having a distal end, the catheter being configured to retain the self-expanding stent proximate the distal end, the catheter including

a tubular member, and

an outer member coaxially positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction;

an inflatable device provided on the catheter, at least a portion of the self-expanding stent overlapping at least a portion of the inflatable device; and

a loading funnel, the loading funnel being configured to be removably attachable to [the] a distal end of the tubular member.

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44. (Amended) A method for implantation of a self-expanding stent, the method comprising:

providing a delivery system including a self-expanding stent, a catheter having a distal end and being configured to retain the self-expanding stent proximate the distal end, an inflatable device provided on the catheter and positioned [either between the self-expanding stent and the distal end or] beneath at least a portion of the self-expanding stent prior to deployment of the self-expanding stent;

delivering the delivery system to a region of a vessel to be repaired;

releasing a portion of the self-expanding stent to a position corresponding with a marker band on the catheter;

re-constraining the self-expanding stent;

implanting the self-expanding stent into a wall of the vessel to be repaired; and

inflating the inflatable device to assist expansion of the self-expanding stent.

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